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Overall, no clinically meaningful changes in vital signs evaluations were associated with VIT-45 administration.

Safety data from more than 1700 subjects demonstrate the safety and tolerability of VIT-45.

What is claimed is:

1. A method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism resulting in reduced bioavailability of dietary iron, comprising administering to a subject in need thereof an iron carbohydrate complex in a single dosage unit of at least 0.7 grams of elemental iron, wherein:

the iron carbohydrate complex is substantially non-immunogenic, and has substantially no cross reactivity with anti-dextran antibodies; and

the iron carbohydrate complex is an iron polyisomaltose complex.

2. The method of claim 1, wherein the disease, disorder, or condition comprises anemia.

3. The method of claim 2, wherein the anemia comprises iron deficiency anemia.

4. The method of claim 2, wherein:

(i) the anemia comprises an iron deficiency anemia associated with chronic blood loss; acute blood loss; pregnancy; childbirth; childhood development; psychomotor and cognitive development in children; breath holding spells; heavy uterine bleeding; menstruation; chronic recurrent hemoptysis; idiopathic pulmonary siderosis; chronic internal bleeding; gastrointestinal bleeding; parasitic infections; chronic kidney disease; dialysis; surgery or acute trauma; chronic ingestion of alcohol; chronic ingestion of salicylates; chronic ingestion of steroids; chronic ingestion of non-steroidal anti-inflammatory agents; or chronic ingestion of erythropoiesis stimulating agents; or

(ii) the anemia is of a chronic disease selected from among rheumatoid arthritis; cancer; Hodgkin's leukemia; non-Hodgkin's leukemia; cancer chemotherapy; inflammatory bowel disease; ulcerative colitis thyroiditis; hepatitis; systemic lupus erythematosus; polymyalgia rheumatica; scleroderma; mixed connective tissue disease; Sjogren's syndrome; congestive heart failure/cardiomyopathy; and idiopathic geriatric anemia; or

(iii) the anemia is due to impaired iron absorption or poor nutrition; or

(iv) the anemia is associated with Crohn's Disease; gastric surgery; ingestion of drug products that inhibit iron absorption; or chronic use of calcium.

5. The method of claim 1, wherein the disease, disorder, or condition is selected from among restless leg syndrome; blood donation; hair loss; and attention deficit disorder.

6. The method of claim 1, wherein the single dosage unit of elemental iron is at least about 1.0 grams.

7. The method of claim 1, wherein the single dosage unit of elemental iron is at least about 1.5 grams.

8. The method of claim 1, wherein the single dosage unit of elemental iron is at least about 2.0 grams.

9. The method of claim 1, wherein the single dosage unit of elemental iron is administered in about 15 minutes or less.

10. The method of claim 1, wherein the single dosage unit of elemental iron is administered in about 5 minutes or less.

11. The method of claim 1, wherein:

mean iron core size is at least about 1 nm but no greater than about 9 nm; or

mean size of a particle of the iron carbohydrate complex is no greater than about 35 nm.

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12. The method of claim 1, wherein the iron carbohydrate complex is administered parenterally.

13. The method of claim 12, wherein:

(i) parenteral administration comprises intravenous infusion and the single unit dose of iron carbohydrate complex is administered at a concentration of about 1000 mg elemental iron in about 200 ml to about 300 ml of diluent; or

(ii) parenteral administration comprises bolus injection and the single unit dose of iron carbohydrate complex is administered at a concentration of about 1000 mg elemental iron in about 200 ml to about 300 ml of diluent; or

(iii) parenteral administration comprises intramuscular injection and the single unit dose of iron carbohydrate complex is administered at a concentration of about 500 mg elemental iron in less than about 10 ml diluent.

14. The method of claim 1, further comprising a second administration of said iron carbohydrate complex upon recurrence of at least one symptom of the disease, disorder, or condition.

15. The method of claim 1, wherein the subject does not experience a significant adverse reaction.

16. The method of claim 1, wherein the iron carbohydrate complex has a pH between about 5.0 to about 7.0; physiological osmolality; an iron core size no greater than about 9 nm; a mean diameter particle size no greater than about 35 nm; and a blood half-life of between about 10 hours to about 20 hours.

17. The method of claim 1, wherein the iron carbohydrate complex contains about 24% to about 32% w/w elemental iron; contains about 25% to about 50% w/w carbohydrate; and has a molecular weight of about 90,000 daltons to about 800,000 daltons.

18. The method of claim 1, wherein the single dosage unit of elemental iron is administered in about 2 minutes or less.

19. The method of claim 1, wherein the single dosage unit of elemental iron is at least about 0.8 grams.

20. The method of claim 1, wherein the single dosage unit of elemental iron is at least about 0.9 grams.

21. The method of claim 1, wherein:

(i) the iron deficiency comprises iron deficiency with chronic blood loss; acute blood loss; pregnancy; childbirth; childhood development; psychomotor and cognitive development in children; breath holding spells; heavy uterine bleeding; menstruation; chronic recurrent hemoptysis; idiopathic pulmonary siderosis; chronic internal bleeding; gastrointestinal bleeding; parasitic infections; chronic kidney disease; dialysis; surgery or acute trauma; chronic ingestion of alcohol; chronic ingestion of salicylates; chronic ingestion of steroids; chronic ingestion of non-steroidal anti-inflammatory agents; or chronic ingestion of erythropoiesis stimulating agents; or

(ii) the iron deficiency is of a chronic disease selected from among rheumatoid arthritis; cancer; Hodgkin's leukemia; non-Hodgkin's leukemia; cancer chemotherapy; inflammatory bowel disease; ulcerative colitis thyroiditis; hepatitis; systemic lupus erythematosus; polymyalgia rheumatica; scleroderma; mixed connective tissue disease; Sjogren's syndrome; congestive heart failure/cardiomyopathy; and idiopathic geriatric anemia; or

(iii) the iron deficiency is due to impaired iron absorption or poor nutrition; or